In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Filed: March 21, 2024

LISA BRANCHEAU,	*	PUBLISHED
Petitioner,	*	No. 21-1209V
v.	*	Special Master Nora Beth Dorsey
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	Dismissal; Influenza ("Flu") Vaccine; Transverse Myelitis ("TM"); One Day Onset.
Respondent.	*	

Maximillian J. Muller, Muller Brazil, LLP, Dresher, PA, for Petitioner.
Nina Ren, U.S. Department of Justice, Washington, DC, for Respondent.

DECISION[1]

I. INTRODUCTION

On April 14, 2021, Lisa Brancheau ("Petitioner") filed a petition for compensation under the National Vaccine Injury Compensation Program ("Vaccine Act" or "the Program"), 42 U.S.C. § 300aa-10 et seq. (2018).[2] Petitioner alleges that she developed transverse myelitis ("TM") as the result of an influenza ("flu") vaccination administered on September 19, 2019. Petition at Preamble (ECF No. 1). Respondent argued against compensation, stating that this

[1] Because this Decision contains a reasoned explanation for the action in this case, the undersigned is required to post it on the United States Court of Federal Claims' website and/or at https://www.govinfo.gov/app/collection/uscourts/national/cofc in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). **This means the Decision will be available to anyone with access to the Internet.** In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, the undersigned agrees that the identified material fits within this definition, the undersigned will redact such material from public access.

[2] The National Vaccine Injury Compensation Program is set forth in Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C. §§ 300aa-10 to -34 (2018). All citations in this Decision to individual sections of the Vaccine Act are to 42 U.S.C. § 300aa.

petition "should be denied and the case should be dismissed." Respondent's Report ("Resp. Rept.") at 1, 14 (ECF No. 16).

After carefully analyzing and weighing the evidence presented in this case in accordance with the applicable legal standards, the undersigned finds that Petitioner has failed to provide preponderant evidence that her flu vaccine caused her TM.[3] Thus, Petitioner has failed to satisfy her burden of proof under Althen v. Secretary of Health & Human Services, 418 F.3d 1274, 1280 (Fed. Cir. 2005). Accordingly, the petition must be dismissed.

II. ISSUES TO BE DECIDED

Diagnosis is not in dispute. See Petitioner's Exhibit ("Pet. Ex.") 14 at 4-5; Resp. Ex. A at 6. At dispute is causation, specifically all three Althen prongs: "(1) whether the [flu] vaccine can cause [TM]; (2) whether [P]etitioner's [TM] was caused by receipt of the vaccination at issue, and; (3) whether the time between [P]etitioner's vaccinations and the onset of symptoms would be considered medically acceptable to infer causation-in-fact." Joint Pre-Hearing Submission ("Joint Submission"), filed Apr. 10, 2023, at 2 (ECF No. 43).

III. BACKGROUND

A. Procedural History

On April 14, 2021, Petitioner filed her petition along with medical records. Petition; Pet. Exs. 1-10. Petitioner filed additional medical records in January and February 2022. Pet. Exs. 11-13. On January 10, 2022, Respondent filed his Rule 4(c) Report, recommending against compensation. Resp. Rept. at 1, 14.

On May 17, 2022, Petitioner filed an expert report from Dr. David Simpson. Pet. Ex. 14. Respondent filed an expert report from Dr. Marcelo Matiello on September 15, 2022. Resp. Ex. A. On January 10, 2023, Petitioner filed a responsive expert report from Dr. Simpson. Pet. Ex. 28.

Thereafter, the parties indicated that they wished to submit this case for adjudication on the record and a briefing schedule was set. Joint Status Rept., filed Feb. 9, 2023 (ECF No. 37); Ruling on the Record Order dated Feb. 9, 2023 (ECF No. 38). Petitioner filed a supplemental declaration on March 16, 2023 and her motion for a ruling on the record on April 10, 2023. Pet. Ex. 35; Pet. Motion for Ruling on the Record ("Pet. Mot."), filed Apr. 10, 2023 (ECF No. 42). Respondent filed his response on June 8, 2023, and Petitioner filed a reply on July 6, 2023. Resp. Response to Pet. Mot. ("Resp. Response"), filed June 8, 2023 (ECF No. 45); Pet. Reply to Resp. Response ("Pet. Reply"), filed July 6, 2023 (ECF No. 46).

[3] TM "describes a heterogeneous collection of acute and subacute infectious and noninfectious inflammatory spinal cord syndromes." Resp. Ex. A-1 at 7 (Dean M. Wingerchuk & Brian G. Weinshenker, Acute Disseminated Encephalomyelitis, Transverse Myelitis, and Neuromyelitis Optica, 19 Continuum 944 (2013)).

This matter is now ripe for adjudication.

B. Factual History

1. Medical History[4]

a. Pre-Vaccination Medical History

Petitioner's past medical history included obesity, high cholesterol, gastroesophageal reflux disease ("GERD"), an overactive bladder/urinary incontinence, hypothyroidism, fatigue, myalgia, arthralgia, and chronic back pain. Pet. Ex. 2 at 27, 40, 46, 65; Pet. Ex. 5 at 11; Pet. Ex. 9 at 10.

On September 4 and 18, 2015, Petitioner presented to chiropractor Charles Gilcher, D.C., P.C. "complaining of discomfort and or paresthesia in the right sacroiliac region." Pet. Ex. 8 at 3-4. Dr. Gilcher diagnosed Petitioner with lumbar, thoracic, and cervical region (multiple sites) subluxation. Id.

On October 5, 2015, Petitioner returned to Dr. Gilcher with the same "complain[t] of discomfort and or paresthesia in the right sacroiliac region," as well as "complain[ts] of discomfort and or paresthesia in the right cervical dorsal region" and "left cervical dorsal region." Pet. Ex. 8 at 5. Dr. Gilcher changed his diagnoses to segmental and somatic dysfunction in the lumbar, thoracic, and cervical regions. Id. Dr. Gilcher continued to treat Petitioner on November 9 and 30, 2015. Id. at 6-7.

Approximately one year later, on October 17, 2016, Petitioner presented to her primary care provider ("PCP") at Metro Shores Internal Medicine ("Metro Shores") reporting a "cramping sensation [that] start[ed] at her right shoulder and [went] down her arm to her hand" and that her right hand would shake. Pet. Ex. 2 at 46. She reported taking naproxen[5] for her symptoms. Id. Petitioner reported she received a flu vaccine at work.[6] Id. at 10, 46. Holle

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[4] This summary of medical records is taken from Petitioner's Motion and Respondent's Response, as the undersigned finds the parties provided an accurate representation of the records. See Pet. Mot. at 2-7; Resp. Response at 3-12.

[5] Naproxen is "a nonsteroidal antiinflammatory drug that is . . . used in the treatment of pain, inflammation, osteoarthritis, rheumatoid arthritis, gout, calcium pyrophosphate deposition disease, fever, and dysmenorrhea and in the prophylaxis and suppression of vascular headache." Naproxen, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=33163 (last visited Mar. 1, 2024).

[6] Petitioner's records indicate Petitioner received a flu vaccine in 2009, 2010, 2012, 2016, 2017, and 2019 (the flu vaccination at issue here). Pet. Ex. 2 at 10. Petitioner's records do not identify, nor does Petitioner argue, any adverse effects related to any vaccination prior to the flu vaccination in 2019. See Pet. Ex. 35 at ¶ 6 (indicating no issues with the flu vaccine prior to 2019).

Janeski, D.O., diagnosed Petitioner with, inter alia, trigger finger of the right thumb, myalgia, tremor of the right hand, and upper extremity pain (central, right). Id. at 46. An X-ray of Petitioner's cervical spine, taken that day, showed "moderate to severe [osteoarthritis] of the neck,"[7] based on "[m]oderate disc degeneration and uncovertebral joint spondylosis[8] bilaterally at the C5-6 and C6-7 levels" and "[f]acet arthritis in the mid right cervical spine." Id. at 261.

On October 28, 2016, Petitioner visited Zubair Sarmast, M.D., at Hand Surgery Associates of Michigan, P.C., to discuss "her right thumb triggering, as well as her mild carpal tunnel symptoms and her right shoulder rotator cuff tendinitis." Pet. Ex. 2 at 22. He treated her trigger finger with a cortisone injection. Id.

Petitioner returned to Dr. Gilcher on multiple occasions for chiropractic care in November and December 2016, variously describing pain in her cervical and thoracic regions that radiated down both arms and pain in her lumbosacral region. Pet. Ex. 8 at 8-17. Dr. Gilcher diagnosed Petitioner with segmental and somatic dysfunction in the lumbar, thoracic, and cervical regions, cervical radiculopathy, muscle spasms, and low back pain. Id.

From approximately January 9 to April 22, 2017, Petitioner continued to complain of and receive treatment for her right trigger thumb. See Pet. Ex. 2 at 57, 62, 139, 141-43; Pet. Ex. 9 at 7, 10-17, 21.

Additionally, on April 18, 2017, Petitioner presented to Metro Shores with "[a]ll over joint pain," constant fatigue, and muscle aches for two weeks. Pet. Ex. 2 at 64. Dr. Janeski diagnosed Petitioner with arthralgia, bilateral hip pain, acute bilateral knee pain, acute bilateral low back pain without sciatica, iron deficiency anemia, and electrolyte imbalance. Id. at 65. An X-ray of Petitioner's lumbar spine taken on April 19, 2017 showed "arthritis and disc degeneration at the L4-5 level with a minimal grade 1 degenerative spondylolisthesis of L4 on L5" and "facet arthritis bilaterally at the L5-S1 level." Id. at 268.

On September 2, 2017, Petitioner went to Oakwood Southshore Medical Center ("Oakwood")[9] Emergency Department ("ED") with right hip pain that radiated to her leg. Pet. Ex. 3 at 222. Review of systems was "[p]ositive for gait problem," secondary to pain. Id. at 223. Physical examination revealed tenderness in right hip and leg. Id. A lumbar spine computed tomography ("CT") showed "[s]pondylitic changes." Id. at 225. Petitioner was

[7] This quote was handwritten on the medical record by an unknown author.

[8] Spondylosis is "ankylosis of a vertebral joint" and "degenerative spinal changes due to osteoarthritis." Spondylosis, Dorland's Med. Dictionary Online https://www.dorlandsonline.com/dorland/definition?id=46749 (last visited Mar. 1, 2024). Ankylosis is the "immobility and consolidation of a joint." Ankylosis, Dorland's Med. Dictionary Online https://www.dorlandsonline.com/dorland/definition?id=2997 (last visited Mar. 1, 2024).

[9] Oakwood Southshore is also referenced as Beaumont Hospital/Health throughout the medical records.

prescribed non-steroidal anti-inflammatory drugs and muscle relaxants and instructed to follow up with her PCP. Id. Petitioner's discharge diagnoses were right leg pain and right-sided sciatica. Id. at 242.

On September 5, 2017, Petitioner followed up with her PCP at Metro Shores for "excruciating pain" in her right hip and through her leg to her knee. Pet. Ex. 2 at 70. Dr. Janeski's diagnoses included acute right-sided low back pain (with sciatica presence unspecified), right lower back radicular pain, and right lower leg iliotibial band syndrome. Id. at 71. Petitioner was prescribed a prednisone taper, narcotic pain medication, back stretches, and ice packs. Id.

On January 2, March 12, and April 24, 2018, Petitioner visited Metro Shores with a cough, pink eye, and a right eye infection, respectively. Pet. Ex. 2 at 75, 81, 87. On each occasion, Petitioner reported thumb locking, low back issues, and tenderness along her iliotibial band. Id. at 79, 85, 92.

On August 21, 2018, Petitioner presented to her PCP at Metro Shores with urinary incontinence. Pet. Ex. 2 at 93. Dr. Janeski diagnosed Petitioner with an overactive bladder and stress incontinence. Id. at 94.

b. Vaccination and Post-Vaccination Medical History

On September 19, 2019, Petitioner saw Dr. Janeski to discuss her continued urinary incontinence. Pet. Ex. 2 at 105. Petitioner reported leakage when she coughed or sneezed and needing "pads all the time." Id. In a handwritten self-evaluation, Petitioner reported she did not have numbness, tingling, wobbliness in legs, unsteadiness, trembling hands, or shaking. Id. at 112. Dr. Janeski's diagnoses included overactive bladder and urinary incontinence. Id. at 106. Petitioner also received a flu vaccine at this visit at 54 years of age. Id. at 10-11; Pet. Ex. 1 at 1.

About two weeks later, on October 3, 2019, Petitioner returned to Dr. Janeski. Pet. Ex. 2 at 115. Petitioner reported "tingling in the last two fingers[] after the flu shot last week," a "pins and needle feeling in both feet at the heels and all toes," and constant numbness and tingling. Id. On physical examination, Dr. Janeski noted Petitioner had "[s]ensation intact [in] bilateral hands and feet, normal gait, [and] no problems walking. Id. at 121. Dr. Janeski diagnosed Petitioner with paresthesia. Id. at 117.

Three days later, on October 6, 2019, Petitioner presented to Oakwood ED "with complaints of generalized weakness and bilateral peripheral neuropathy for the past two weeks since she received a flu vaccination in her right upper extremity." Pet. Ex. 3 at 108. Petitioner "state[d] that the morning following . . . the vaccination, she woke with paresthesia in her [fourth] and [fifth] upper extremity digits bilaterally as well as paresthesia in her bilateral feet." Id. She explained "her symptoms ha[d] gradually progressed since onset and now involve[d] her entire hands and feet." Id. Petitioner reported her numbness and tingling in both hands and feet "started after [the] flu shot" and had been "getting progressively worse [over the] last [two] weeks" and "now . . . travelled up her arms and legs." Id. at 94, 113. Petitioner "denie[d] history of [] recent infections, fevers, difficulty walking or carrying items, shortness of breath,

headache, visual symptoms, speech changes, chest pain, abdominal pain, trauma, bowel or bladder incontinence, [and] rashes." Id. at 108. Physical examination revealed tachycardia and tremors, but was otherwise normal. Id. at 110. A head CT was also normal. Id. at 111. A cervical spine CT showed "[s]pondylosis and spondyloarthrosis[10] at C5-C6 and C6-C7." Id. The attending ED provider, Karla Kasza, D.O., ordered a neurology consult and admitted Petitioner with an initial assessment of peripheral neuropathy, generalized weakness, and cervical spinal canal stenosis. Id. at 105, 111-12.

On October 7, 2019, Petitioner was evaluated by neurologist Christopher Whitty, M.D. Pet. Ex. 3 at 120. Petitioner reiterated her complaints of tingling in her hands and feet that had worsened over the last two weeks following receipt of a flu vaccination. Id. Dr. Whitty documented that Petitioner "fe[lt] that she ha[d] weakness and a heavy sensation that [was] traveling up her arms and legs." Id. Petitioner reported "[n]o fever or chills, no nausea/vomiting, no diarrhea/constipation, no shortness of breath/cough, no headache, no changes in vision, no changes in urination, no rashes." Id. at 122. Neurological examination was normal. Id. Dr. Whitty recommended an outpatient electromyography ("EMG")/nerve conduction study ("NCS").[11] Id. He did not believe Petitioner had Guillain-Barré syndrome ("GBS").[12] Id.

That same afternoon, Dr. Kasza evaluated Petitioner and explained that, despite Petitioner's concerns, there was no evidence to suggest she had GBS. Pet. Ex. 3 at 114. Dr. Kasza added that "[t]here was no evidence of ascending weakness" and neurology confirmed her reflexes and strength were normal. Id. Dr. Kasza believed Petitioner's cervical spine disease "could certainly be giving [Petitioner] some of the pain and tingling in her fingertips." Id. On examination, Dr. Kasza observed decreased cervical and lumbar lordosis,[13] "tissue texture changes in the cervical spine bilaterally," and "[m]ajor correlations with the musculoskeletal system." Id. at 116. Petitioner was prescribed Neurontin for the nerve pain as well as anti-inflammatories, directed to follow up with neurology for an EMG, and was discharged. Id. at 88, 114.

On October 11, 2019, Petitioner returned to Dr. Gilcher. Pet. Ex. 8 at 18-19. Petitioner reported that prior to her flu vaccination on September 19, 2019, "she had some neck tightness occasionally in her upper back and neck" two to three times per week and she rated the "tight feeling . . . as a level 5." Id. at 18. She attributed the neck tightness to stress and treated it with

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[10] Spondyloarthropathy is the "disease of the joints of the spine." Spondyloarthropathy, Dorland's Med. Dictionary Online https://www.dorlandsonline.com/dorland/definition?id=46736 (last visited Mar. 1, 2024).

[11] Petitioner does not appear to have pursued the referral for an EMG/NCS.

[12] "GBS is an acute monophasic peripheral neuropathy." 42 C.F.R. § 100.3(c)(15)(i).

[13] Lordosis is "a dorsally concave portion of the vertebral column." Lordosis, Dorland's Med. Dictionary Online https://www.dorlandsonline.com/dorland/definition?id=28750 (last visited Mar. 1, 2024).

monthly massages. Id. Petitioner also alleged she "experienced new symptoms" the day after her flu vaccine, or on September 20, 2019. Id. Dr. Gilcher wrote Petitioner described

> [n]umbness, pins and needles in hands and fingers bilaterally and equal []on both sides and equal in all fingers and thumbs. [T]he intensity level is an 8-9 and is constant and does [not] go away. The intensity gradually increased daily until it reached its current level of 9. She is also getting weakness []in her arms bilaterally and they fatigue easily and she has cramping in her elbows and shoulders bilaterally that comes and goes[.] [Petitioner] also developed similar symptoms in both of her feet with numbness and pins and needles into both feet. These symptoms also began the day following the flu shot and came on gradually and have reached an intensity level of a 4. She also feels that she has cramping feeling of both ankles that comes and goes and can be right side, left side[,] or both with no pattern. . . . [She] also developed a feeling of pressure in her head causing her to have a constant headache that is rated as a 7. The pressure is behind both eyes and the back of her neck and on the sides of her head behind both ears.

Id. Petitioner returned on October 14 and October 16, 2019 with "symptoms [that] ha[d] continued to increase over the last couple days as she ha[d] more fatigue in her arms and more cramping in her wrists[,] [] elbows[,] and shoulders." Id. at 20, 22 (emphasis omitted). On both occasions, Petitioner stated that "her ability to walk ha[d] changed" and that she was "a little jerky or less fluid with her movement." Id. (emphasis omitted).

Petitioner followed up with Dr. Kasza on October 14, 2019 and requested a second opinion and lumbar puncture. Pet. Ex. 2 at 122. Dr. Kasza summarized Petitioner's clinical course and noted Petitioner "fe[lt] her weakness [was] worse-her legs [felt][] weak and again persistent tingling." Id. Petitioner did not have shortness of breath but was very anxious. Id. Petitioner "was sure she had GB[S] and is a nurse and went to CDC website." Id. Dr. Kasza "explained in detail that [n]eurology [] did not think [there were] any symptoms of GB[S]" and indicated that she cannot order a lumbar puncture as "[n]eurology typically orders this type of testing if needed." Id. Physical examination was unremarkable. Id. at 128-29. Diagnoses included weakness of bilateral lower extremities and paresthesia of bilateral hands and legs. Id. at 124-45. Dr. Kasza renewed Petitioner's Neurontin prescription and referred her to neurologist Fadi Delly, M.D. Id. at 125.

Two days later, on October 16, 2019, Petitioner saw Dr. Delly, describing her clinical course, reporting "tingling in her fingers and toes" the day after vaccination. Pet. Ex. 10 at 1. Petitioner noted "weakness in her arms and legs," fatigue, and temperature changes in her fingers. Id. Petitioner also reported a new and severe aching, burning, and cramping pain, accompanied by constant numbness and tingling in both wrists, hands, and elbows that was "rapidly worsening." Id. On examination, Petitioner had a positive Romberg test, a "slight sway" in her gait, normal strength, normal reflexes, and a sensory deficit. Id. at 4. Dr. Delly diagnosed Petitioner with cervical radiculopathy, a balance problem, numbness and tingling, and cervical spondylosis. Id. at 4-5. A cervical spine magnetic resonance imaging ("MRI") and

EMGs were ordered. Id. at 5. Petitioner was advised to return in a week and go to the ED if symptoms worsened. Id. at 5.

On October 20, 2019, Petitioner returned to Oakwood ED complaining of "'nerve pain' [in] [bilateral] hands and feet since receiving the flu shot on [September 19, 2019]," as well as neck pain. Pet. Ex. 4 at 39, 41. She indicated her arms felt heavy and she had leg weakness. Id. at 52. Petitioner "describe[d] her symptoms as [] constant and worsening since [] onset." Id. Petitioner reported "no abdominal pain, no chest pain, no congestion, no cough, no diarrhea, no fatigue, no fever, no headaches, no nausea, no shortness of breath, no vomiting[,] and no wheezing." Id. Examination conducted by Jonathan Leischner, D.O., was normal. Id. at 54. Petitioner was admitted for observation under Andrew Zazaian, D.O., internal medicine, and for a neurology consultation. Id. at 56. A lumbar puncture was ordered and conducted that night in the ED. Id. at 52, 57.

The following day, October 21, Petitioner was examined by Dr. Zazaian. Pet. Ex. 4 at 59. Petitioner reported developing "a pins and needles sensation in her fourth and fifth digits of bilateral hands along with her toes" on September 20, 2019, which "then progressed to all the fingers on her hands along with her elbows and dorsum of bilateral feet." Id. at 60. "[S]he denied any weakness but felt as though her extremities were 'tired.'" Id. Petitioner denied saddle paresthesias, loss of bowel or bladder function, low back pain, or neck pain. Id. Petitioner expressed concern that she had GBS. Id. Her physical examination and brain MRI and magnetic resonance angiograph ("MRA") were all normal. Id. at 62, 65. Dr. Zazaian's differential diagnoses were paresthesias of bilateral upper and lower extremities and cervical radiculopathy. Id. at 65.

Later that day, Petitioner had a neurology consultation with Amy Kodrik, D.O. Pet. Ex. 4 at 69. Petitioner summarized her clinical course and maintained "her symptoms first developed on [September 20, 2019]." Id. at 70. An outpatient cervical spine MRI report confirmed degenerative changes at C5-C6 and C6-C7. Id. Neurological examination revealed motor testing of 5/5 in all extremities; 2/4 reflexes in biceps, triceps, brachioradialis, patellar, and trace at the Achilles; and plantar response down going bilaterally. Id. at 73. Dr. Kodrik found no evidence for acute inflammatory demyelinating polyneuropathy ("AIDP"). Id. at 70. Petitioner's cerebrospinal fluid ("CSF") protein was normal. Id. Petitioner had mild degenerative joint disease but was otherwise unremarkable. Id. Dr. Kodrik concluded Petitioner was "stable for discharge from a neurologic standpoint." Id.

Petitioner also had a neurosurgery consultation on October 21 with Fred Song Junn, M.D. Pet. Ex. 4 at 73-74. Petitioner recounted her symptoms and clinical course. Id. "She stated that she noticed the issue of paresthesias shortly after receiving the flu vaccine last month, approximately September 19." Id. at 74. Dr. Junn noted "[h]er examination show[ed] subjective paresthesia affecting the upper extremity to the wrists bilaterally." Id. Dr. Junn also noted Petitioner's cervical spine MRI without contrast "show[ed] a T2 signal change in the upper cervical region without expansion." Id. Differential diagnoses included "inflammatory myelitis

versus neoplasm"[14] and he ordered a cervical spine MRI with contrast. Id. Petitioner was started on intravenous steroids. Id. at 79, 98.

On October 22, 2019, Petitioner attended inpatient physical therapy ("PT") and occupational therapy ("OT") evaluations. Pet. Ex. 4 at 87-95. At PT, Petitioner reported "numb patches on the bottom of feet." Id. at 88. The physical therapist recommended outpatient PT and a wheeled walker. Id. at 90. At OT, Petitioner additionally reported "burning/numbness sensation in [both] hands" and hypersensitivity. Id. at 93. The occupational therapist recommended a shower chair and outpatient OT for the decreased sensation in her hands. Id. at 95. Petitioner was seen again by OT on October 23. Id. at 83-86.

On October 23, 2019, Dr. Junn reviewed Petitioner's cervical spine MRI, performed on October 22, 2019, which appeared to show "inflammatory changes of the spinal cord." Pet. Ex. 4 at 103, 132-33. Specifically, the MRI showed "[a]bnormal hyperintense T2 intramedullary signal within the spinal cord at C2-C3 with subtle associated enhancement. Findings nonspecific[,] however[,] suspect[ed] to be demyelinating in nature or inflammatory in nature considering presentation of symptoms following flu vaccine[,] however clinical correlation is recommended. Neoplasm [was] not entirely excluded." Id. at 27, 103. Dr. Junn determined that Petitioner did not require surgical intervention, and he recommended steroids, a repeat cervical spine MRI, and continued Neurontin, but otherwise deferred treatment to neurology. Id. at 103.

Subsequently, Dr. Kodrik called Petitioner to discuss the cervical spine MRI, which she opined was consistent with "[TM] from recent flu[] vaccination." Pet. Ex. 4 at 104. Prednisone taper and continued use of Neurontin were recommended, as well as follow up and repeat cervical spine MRI. Id. Thereafter, Dr. Zazaian discharged Petitioner home on October 23. Id. at 32, 83, 104.

On December 19, 2019, Petitioner saw Dr. Kodrik in follow up to her hospitalization. Pet. Ex. 5 at 22. Petitioner recalled that "[s]he developed severe burning pain and numbness in her upper extremities within 24 hours of the flu vaccination." Id. Petitioner felt the steroids "[h]elped significantly" and had stopped taking Neurontin "over the last few weeks since her symptoms have improved." Id. She no longer experienced numbness but complained of Lhermitte's[15] and a "band like sensation around her thorax" that occurred "[two] weeks ago[,] [l]asted for several minutes[,] and then resolved." Id. at 22, 24. Dr. Kodrik's assessment was numbness and TM. Id. at 24. Petitioner was instructed to follow up after she completed updated cervical and thoracic spine MRIs. Id.

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[14] Neoplasm is "any new and abnormal growth; specifically a new growth of tissue in which the growth is uncontrolled and progressive." Neoplasm, Dorland's Med. Dictionary Online https://www.dorlandsonline.com/dorland/definition?id=33438 (last visited Mar. 1, 2024).

[15] Lhermitte sign is "the development of sudden, transient, electric-like shocks spreading down the body when the patient flexes the head forward; seen mainly in multiple sclerosis but also in compression and other disorders of the cervical cord." Lhermitte Sign, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=106344 (last visited Mar. 1, 2024).

At this visit, Dr. Kodrik provided Petitioner with "documentation that she [was] not to have the [flu] vaccination in the future." Pet. Ex. 5 at 24. This letter stated, "[Petitioner] is under my neurologic care and is unable to receive the [flu] vaccination as she has a history of [TM] associated with the [flu] vaccination." Id. at 20.

On December 27 and 31, 2019, Petitioner sought treatment from Dr. Gilcher without reporting any new symptoms. Pet. Ex. 8 at 24-27.

Petitioner's thoracic spine MRI, performed on January 10, 2020, showed "[m]inimal degenerative changes" and "[n]o intramedullary cord signal lesions . . . to suggest demyelination." Pet. Ex. 5 at 27. Petitioner's cervical spine MRI, performed that same day, showed degenerative changes without central canal stenosis, neural foraminal stenosis, a "[l]ess pronounced/smaller demyelinating lesion at C3-4 with no enhancement," and "[n]o new demyelinating lesions." Id. at 28. Dr. Kodrik concluded that Petitioner's TM was "improving/healing." Id. at 30.

On February 11, 2020, Petitioner followed up with Dr. Kodrik and reported "[s]he [was] having intermittent symptoms usually exacerbated by stress or upper extremity activity." Pet. Ex. 5 at 32. She still experienced "Lhermitte's with neck movement," but she no longer felt the "'band' around her abdomen." Id. Dr. Kodrik decided to "hold off on treatment for breakthrough symptoms" as Petitioner's "symptoms [were] improving." Id. at 34. Petitioner was instructed to follow up in six months, in October. Id.

Petitioner retuned to Dr. Kodrik on October 7, 2020. Pet. Ex. 6 at 3. Petitioner reported "[s]he continue[d] to have high blood pressure issues since [] episode of [TM]." Id. Petitioner said her incontinence had improved since October 2019. Id. She rarely experienced "Lhermitte's with neck movement." Id. "No pain or new symptoms" were reported. Id. Dr. Kodrik noted Petitioner was present "for [a] re-evaluation of history of C3-4 [TM] following a[] [flu] vaccination with rare intermittent breakthrough symptoms." Id. at 6. Dr. Kodrik continued to "hold off on treatment for breakthrough symptoms" and instructed Petitioner to follow up "as needed." Id.

In a letter dated September 23, 2021, Angela D. Brennan, N.P., at Dr. Kodrik's office, wrote Petitioner was under Dr. Kodrik's care for TM. Pet. Ex. 11 at 54. Additionally, the letter stated, "[Petitioner] received the flu vaccine back in 2019 and she had a reaction [] which caused the [TM]. [Petitioner] should be exempt from receiving the Covid [v]accine . . . ." Id.

No additional medical records were provided.

2. Petitioner's Declaration

Prior to the subject flu vaccination on September 19, 2019, Petitioner was on medication for GERD and her thyroid, had no pre-existing neurological issues, and received treatment from a chiropractor for her back. Pet. Ex. 35 at ¶ 2; Pet. Ex. 7 at ¶ 3.

At the time of vaccination, Petitioner was a registered nurse who received yearly flu vaccinations from her employer. Pet. Ex. 35 at ¶¶ 1, 3. On September 19, 2019, Petitioner received a flu vaccine while at her doctor's office. Id. at ¶ 3; Pet. Ex. 7 at ¶ 2. On the day of vaccination, "nothing unusual" occurred after her vaccination. Pet. Ex. 35 at ¶ 3.

The next day, September 20, 2019, Petitioner "noticed a very faint sensation of pins and needles in [her] hands and last two toes. It was very faint, hardly noticeable and [she] figured [she] slept in an odd position or something and it would resolve on its own." Pet. Ex. 35 at ¶ 4. "Within a week[,] the sensation in [her] fingers and toes was [] more pronounced." Id. at ¶ 5. She would "shak[e] [her] hands . . . and stomp[] [her] feet to alleviate the feeling," but "[t]he sensation continued without relief." Id. Petitioner added "the sensation [was] becoming more pronounced" and "spread[] from the finger tips [to] the entire fingers" and from her toes to "numb patches on the bottoms of [her] feet." Id.

She began to investigate her symptoms and equated them to symptoms of GBS. Pet. Ex. 35 at ¶ 6. Petitioner went to her doctor[16] and shared her symptoms and concerns. Id. at ¶ 7. She disagreed with her doctor that it was electrolyte imbalance or vitamin deficiency, and later went to the ED when her symptoms continued to worsen. Id. at ¶¶ 7-8. At the time of her ED visit,[17] "[her] entire hand had the pins and needles sensation with an added burning pain in the palms of [her] hands. [Her] feet also had the increased sensation of pins and needles but [she had] more pronounced numbness patches which felt like [she] was walking on spongy material." Id. at ¶ 8. She "felt like [her] legs could give out, but [she] felt the spongy sensation on the soles of [her] feet which was throwing off [her] balance." Id. Petitioner also reported "cramping down [her] arms and legs with increased fatigue with little exertion," including fatigue with holding her cell phone and walking short distances. Id. At the ED she "[u]tiliz[ed] [her] own medical training" and explained her symptoms and concerns. Id. at ¶ 9. "[She] tried to be as accurate as possible, so an accurate and speedy diagnosis could be made and corrective action taken." Id. She was told her symptoms were due to degeneration in her neck and she was prescribed Neurontin. Id. at ¶ 10.

Petitioner explained her symptoms continued to progress and she did not find the Neurontin effective. Pet. Ex. 35 at ¶ 11. She "was having great difficulty working." Id. She was experiencing pain in her hands and fingers and cramping in her arms and legs. Id. Petitioner returned to her chiropractor, but the adjustments were not effective. Id. at ¶ 12. Her symptoms continued to worsen and she requested a lumbar puncture at a follow-up appointment

[16] Although Petitioner did not indicate the date of this visit, she first saw a provider post-vaccination on October 3, 2019. See Pet. Ex. 35 at ¶ 7; Pet. Ex. 2 at 115.

[17] Petitioner did not indicate the date of this visit in her declaration. See Pet. Ex. 35 at ¶ 8. However, an examination of the medical records reveals Petitioner's first ED visit post-vaccination was October 6, 2019. See Pet. Ex. 3 at 108.

with Dr. Kasza.[18] Id. at ¶¶ 13-14. Petitioner stated Dr. Kasza told her there was "nothing to indicate . . . an autoimmune disease." Id. at ¶ 14. Dr. Kasza gave Petitioner a referral to neurologist, Dr. Delly. Id. By the time Petitioner saw Dr. Delly,[19] she "developed a jerking motion when ambulating[] in addition to all the other symptoms." Id. at ¶ 15. Petitioner averred she "tried to be as accurate as possible." Id. An MRI was ordered. Id.

She returned to the ED,[20] received blood work, lumbar puncture, X-rays, and MRIs, and was diagnosed with TM. Pet. Ex. 35 at ¶¶ 17-18. She averred that neurosurgeon Dr. Junn told her TM "was rare and was caused by an autoimmune response to the [flu] vaccine." Id. at ¶ 18. Petitioner received intravenous steroids for three days before she was discharged. Id. at ¶¶ 18-19.

Petitioner averred she had "periodic symptoms," including "an electrical shock that would travel down her spinal cord or a sensation of a tight band around [her] upper torso that affected [her] breathing," "[f]or at least a year." Pet. Ex. 35 at ¶ 21. She "ha[s] been advised by [her] neurologist and primary care physician not to get any other vaccines in the future." Id. Petitioner declared "[a]s a result of [her] vaccination, [she] developed [TM] and she "suffered no other injuries or accidents that would explain [her] [TM]. Pet. Ex. 7 at ¶¶ 4-5.

C. Expert Reports

1. Petitioner's Expert, Dr. David M. Simpson M.D.[21]

a. Background and Qualifications

Dr. Simpson is a Neurology Professor and the Director of the Neuromuscular Division and Clinical Neurophysiology Laboratories at the Icahn School of Medicine at Mount Sinai Hospital, where he has worked as an Attending Neurologist since 1984. Pet. Ex. 14 at 1. After receiving his M.D. from SUNY at Buffalo School of Medicine in 1979, he completed an internal medicine internship at University Hospitals of Cleveland, Case Western Reserve in Ohio, a neurology residency at Cornell University Medical Center in New York, and a clinical neurophysiology fellowship at Massachusetts General Hospital. Pet. Ex. 15 at 1. He is board certified in neurology, with subspecialty certifications in clinical neurophysiology and neuromuscular medicine, and electrodiagnostic medicine. Id. He is a member of various

[18] Petitioner did not indicate the date of this follow up visit in her declaration, but a review of the medical records indicates Petitioner requested a second opinion and lumbar puncture at her follow-up appointment with Dr. Kasza on October 14, 2019. See Pet. Ex. 35 at ¶ 14; Pet. Ex. 2 at 122.

[19] Medical records indicate Petitioner saw Dr. Delly on October 16, 2019. Pet. Ex. 10 at 1.

[20] Medical records show Petitioner next returned to the ED on October 20, 2019. Pet. Ex. 4 at 39.

[21] Petitioner submitted two expert reports from Dr. Simpson. Pet. Exs. 14, 28.

professional societies and has extensively published, presented, and lectured on central and peripheral neurological disorders. Id. at 3, 20-94; Pet. Ex. 14 at 1. Dr. Simpson's "specialty areas in neurology include neuromuscular disorders, neuro-infectious disease, and clinical use of botulinum toxin. [He] ha[s] diagnosed and treated many patients with GBS over the course of [his] career[;] [he] teach[es] medical students, neurology residents[,] and EMG/Neuromuscular Fellows about [GBS;] and [he] frequently lecture[s] on GBS." Pet. Ex. 14 at 1.

b. Opinion

Dr. Simpson opined that "more likely than not," Petitioner's flu vaccine is "causally related to [her] development of TM." Pet. Ex. 28 at 1; see also Pet. Ex. 14 at 9. Dr. Simpson found "the sequence of events, with neurological symptoms beginning as early as one day following [flu] vaccine, followed by progressive neurological signs of TM, with consistent spinal MRI findings, support the diagnosis of TM." Pet. Ex. 14 at 9. In addition, "[t]here is a strong biological rationale and ample evidence in the medical literature that [the flu] vaccine is associated with TM." Id. He further stated Petitioner's "treating physicians repeatedly documented a causal association," there was "no alternative explanation for causation," and "[t]he temporal relationship support[s] that TM was related to vaccination." Id.

i. Diagnosis

Dr. Simpson opined Petitioner "exhibited clinical symptoms and signs consistent with TM, with typical MRI findings," and "[a]ll [] treating physicians concurred with the diagnosis of TM." Pet. Ex. 14 at 4-5. Dr. Simpson also noted that Respondent's expert, Dr. Matiello, agreed with the diagnosis of TM. Pet. Ex. 28 at 1.

ii. Althen Prong One

To explain how the flu vaccine can cause TM, Dr. Simpson opined "the most likely mechanism is molecular mimicry."[22] Pet. Ex. 14 at 5. He explained that molecular mimicry is the concept by which shared structures in a vaccine can trigger a cross-reactive response to self, leading to an immune response that can cause inflammation in the spinal cord that is seen in TM. Id. (citing Pet. Ex. 18 at 8 ("Molecular mimicry may occur when an immune response mounted against an environmental antigen cross-reacts with a host antigen, which in turn leads to autoimmunity, organ-specific damage, and possibly disease.")).[23]

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[22] Dr. Simpson noted "[t]here are numerous biologic mechanisms by which vaccines may lead to neurologic illness, including direct neurotoxic effects and development of autoimmunity, in which the vaccine's antigenic effects result in an abnormal immunologic response." Pet. Ex. 14 at 5. He also noted other "potential mechanisms," including "[n]eurotoxic effect," "[i]mmune complex formation," and "[l]oss of self-tolerance." Id. Because Dr. Simpson did not discuss these concepts or mechanisms more fully, or explain how they were at play here, the undersigned does not discuss them in her Decision.

[23] Michel C. Levin et al., Neuronal Molecular Mimicry in Immune-Mediated Neurologic Disease, 44 Annals Neurology 87 (1998).

In response to Dr. Matiello's argument that Dr. Simpson did not provide specific homology, Dr. Simpson acknowledged it is not known and argued testing for specific homology is not standard when assessing patients. Pet. Ex. 28 at 2.

Additionally, "[w]hile it is true that our understanding of the primary pathogenetic mechanisms of TM is incomplete, it is certainly tenable that innate immunological mechanisms, triggered by molecular mimicry, underlies the pathogenesis of vaccine-induced TM as proposed by numerous authors." Pet. Ex. 28 at 2. He did not explain what he meant by "innate immunological mechanisms, triggered by molecular mimicry." Nor did he explain who the "numerous authors" were.

To support his theory of molecular mimicry, Dr. Simpson cited literature discussing an association between vaccinations and TM,[24] including case reports documenting the development of TM following flu vaccination. Pet. Ex. 14 at 5. He first cited Fenichel (1982)[25] and noted several case reports of TM were discussed by the author. Id. (citing Pet. Ex. 20). Fenichel reviewed adverse events following multiple vaccines, including TM following the flu vaccine. Pet. Ex. 20 at 4. Fenichel noted "[r]abies and smallpox are the only associated immunizations" with TM and "data concerning a cause-and-effect relationship between immunization and []TM is circumstantial and based upon the temporal relationship." Id. Fenichel discussed only one article related to TM post-flu vaccination, which was not cited in this matter. Id. This article was a case report of two patients who developed TM seven and 29 days following flu vaccination. Id. Vaccine causation was not discussed by Fenichel. See id.

Next, Dr. Simpson cited Agmon-Levin et al. (2009),[26] "a comprehensive literature review" that "identified 37 reported cases of TM following vaccination of various types." Pet. Ex. 14 at 5 (citing Pet. Ex. 21). Two of the 37 cases of TM followed flu vaccination. Pet. Ex. 21 at 2. The authors noted "[t]he rarity of post-[flu]-vaccination neurological complications reported in recent years makes it impossible to establish a definite causal relation." Id. at 4. However, they discussed mechanisms by which vaccines may induce TM, and acknowledged

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[24] Although the undersigned reviewed all of the medical literature, she does not discuss the literature cited by Dr. Simpson that does not relate to the material issues here or that was not discussed or mentioned in his reports. See Pet. Ex. 19 (discussing two case reports of giant cell arteritis post-flu vaccine and rheumatoid arthritis post-flu and tetanus toxoid vaccines) (Maria Antonia Pou et al., Development of Autoimmune Diseases After Vaccination, 14 J. Clinical Rheumatology 243 (2008)); Pet. Ex. 34 (Silva Markovic-Plese et al., High Level of Cross-Reactivity in Influenza Virus Hemagglutinin-Specific CD4+ T-Cell Response: Implications for the Initiation of Autoimmune Response in Multiple Sclerosis, 169 J. Neuroimmunology 31 (2005)).

[25] Gerald M. Fenichel, Neurological Complications of Immunization, 12 Annals Neurology 119 (1982).

[26] N. Agmon-Levin et al. Transverse Myelitis and Vaccines: A Multi-Analysis, 18 Lupus 1198 (2009). This article was also cited by Respondent's expert. Resp. Ex. A-8.

"[m]olecular mimicry between infectious antigens and self antigens is the most common mechanism." Id. (emphasis omitted). Agmon-Levin et al. added that a "host's response to a vaccine, originally generated to produce protective immunity, is similar to its response to an infectious invasion." Id. The authors concluded that "the temporal association between [] vaccines and TM, and the possible mechanism associating these phenomena cannot be ignored. The rarity of TM makes it a difficult disease to study." Id. at 5.

Dr. Simpson also cited "a case of acute TM following tetanus toxoid vaccination" discussed in Read et al.[27] Pet. Ex. 14 at 5 (citing Pet. Ex. 22). Read et al. discussed a case of a 50-year-old man who received a tetanus toxoid booster vaccination after suffering a penetrating foot wound. Pet. Ex. 22 at 1. The patient was diagnosed with a viral illness about ten days later after complaining of myalgia, lethargy, fatigue, and mild bifrontal headache. Id. Twelve days after initial presentation, he was admitted to the hospital with "flaccid, areflexic paralysis of the legs, associated with sensory loss to T6, moderately severe midthoracic back pain, and urinary retention." Id. After diagnostic testing, he was diagnosed with acute TM. Id. at 2. The authors concluded that "[a]lthough it is possible that the myelopathy in [their] patient occurred independently of vaccination, the timing and absence of an alternative explanation may implicate tetanus toxoid." Id.

Akkad et al.,[28] another case report cited by Dr. Simpson, concerned a patient who developed TM four days after receipt of a flu vaccine. Pet. Ex. 14 at 5 (citing Pet. Ex. 23). Following extensive laboratory testing, "effectively eliminat[ing] the most probable causes for [their] patient's condition, [the authors] attributed it to postvaccination TM following novel [flu] A(H1N1) vaccination." Pet. Ex. 23 at 2. The authors noted "vaccine-associated TM cases are . . . scarce," but have been reported to occur following administration with various vaccines, including the flu vaccine. Id. They added that "the temporal relationship of TM with such a wide variety of vaccines suggest[s] . . . that a common denominator such as an adjuvant might trigger the syndrome;" however, because "[t]he 2009 novel [flu] A(H1N1) vaccines[] [] do not contain an adjuvant[,] . . . it is something other than the adjuvant in [their] case." Id.

Korn-Lubetzki et al.[29] similarly reported a case of TM following flu vaccination. Pet. Ex. 24. Their patient developed symptoms one month following flu H1N1 (Focetria)[30] vaccination. Id. at 1. Testing was consistent with TM. Id. A complete etiological workup was negative. Id.

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[27] Stephen J. Read et al., Acute Transverse Myelitis After Tetanus Toxoid Vaccination, 339 Lancet 1111 (1992).

[28] Wafa Akkad et al., Longitudinally Extensive Transverse Myelitis Following Vaccination with Nasal Attenuated Novel Influenza A (H1N1) Vaccine, 67 Archives Neurology 1018 (2010).

[29] Isabelle Korn-Lubetzki et al., H1N1 Vaccine-Related Acute Transverse Myelitis, 13 Isr. Med. Ass'n J. 249 (2011).

[30] Focetria is an adjuvanted flu vaccine. Focetria, Eur. Meds. Agency, https://www.ema.europa.eu/en/medicines/human/EPAR/focetria (last updated Feb. 11, 2016). Petitioner did not file evidence to show there was an adjuvant in her flu vaccine.

at 2. The authors found "[t]he fact that the symptoms and signs had occurred a month after the H1N1 vaccination suggest[ed] the pathogenesis of post-vaccinal myelitis due to an immunological reaction to the vaccine." Id. They hypothesized that because the vaccine their patient received contained an adjuvant, the adjuvant may have had a "role . . . in the development of an immune mediated neurological complication." Id.

In his supplemental expert report, Dr. Simpson "agree[d] with Dr. Matiello that the literature providing an association between [flu] vaccination and TM is provided predominantly in case reports and series." Pet. Ex. 28 at 2. However, he explained that "the detection of rare effects of vaccines and other therapeutics are often not found in initial prospective, placebo-controlled trials, as they are underpowered to detect such low-incidence occurrences." Id. (citing Pet. Ex. 30 at 1 ("Post-licensure monitoring may be superior to pre-licensure reviews in detecting rare adverse events.")).[31] For support, he cited to the 2012 Institute of Medicine ("IOM") report,[32] where the Chair of the Committee, Dr. Ellen Wright Clayton, stated that "some issues simply cannot be resolved with currently available epidemiological data . . . . In addition, even very large epidemiological studies may not detect or rule out rare events." Id. (quoting Pet. Ex. 25 at 10-11); see also Pet. Ex. 31 at 2 (indicating "epidemiological studies focusing specifically on [autoimmune disease] risk have remained few and their power to detect any increase in rare events was limited").[33]

Dr. Simpson concluded "[t]here is a strong biological rationale and ample evidence in the medical literature that [the flu] vaccine is associated with TM." Pet. Ex. 14 at 9.

iii. Althen Prong Two

Dr. Simpson opined the sequence of events in this case supports a finding that Petitioner's flu vaccination caused her to develop TM within one day of vaccination. Pet. Ex. 14 at 5-6, 9. First, he explained Petitioner developed rapidly progressive sensory and motor symptoms in her upper and lower extremities typical of TM. Id. at 5. Her early neurological examinations were unremarkable, however, she was later found to have "diffuse hyperreflexia and [an] unsteady gait, indicative of corticospinal tract abnormalities consistent with myelopathy/myelitis." Id. Her cervical spine MRI revealed a T2 hyperintense signal with associated contrast enhancement, which Dr. Simpson also noted was consistent with TM. Id.

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[31] Louise Brinth et al., Suspected Side Effects to the Quadrivalent Human Papilloma Vaccine, 62 Danish Med. J. 1 (2015). Even though this study concerns only the human papillomavirus vaccine, and does not discuss the flu vaccine or TM, Dr. Simpson maintained "the concept is clearly transferable to rare neurological events associated with other vaccines, such as TM following [flu] vaccination in the current case." Pet. Ex. 28 at 3.

[32] Inst. of Med., Adverse Effects of Vaccines: Evidence and Causality (Kathleen Stratton et al. eds., 2012).

[33] Sara Miranda et al., Human Papillomavirus Vaccination and Risk of Autoimmune Diseases: A Large Cohort of Over 2 Million Young Girls in France, 35 Vaccine 4761 (2017). TM and the flu vaccine were not investigated or discussed in this study. See supra note 31.

Thereafter, Petitioner received steroid treatment, which Dr. Simpson noted improved Petitioner's symptoms as is typically seen in TM patients. Id. at 6. Additionally, residual neurological symptoms and deficits, which Petitioner has, can persist following treatment. Id. at 6, 9.

Regarding Petitioner's pre-existing symptoms of joint pain and carpal tunnel syndrome, Dr. Simpson agreed these symptoms were not consistent with a myelopathy or myelitis. Pet. Ex. 14 at 6.

Additionally, he noted Petitioner's "treating physicians repeatedly documented a causal association between the flu vaccine and the onset of her TM, in the absence of any other identifiable factor." Pet. Ex. 14 at 9. He noted that Dr. Kodrik, on October 23, 2019, told Petitioner her cervical spine MRI was consistent with "[TM] from recent flu[] vaccination." Pet. Ex. 4 at 104; see Pet. Ex. 14 at 4. At a visit on December 19, 2019, Dr. Kodrik provided Petitioner with "documentation that she [was] not to have the [flu] vaccination in the future." Pet. Ex. 5 at 24; see Pet. Ex. 14 at 4. And in a letter dated September 23, 2021, Nurse Brennan at Dr. Kodrik's office wrote "[Petitioner] received the flu vaccine back in 2019 and she had a reaction in which caused the [TM]. [Petitioner] should be exempt from receiving the Covid [v]accine [so that] [] this reaction does not occur again." Pet. Ex. 11 at 54; see Pet. Ex. 14 at 4.

Further, Dr. Simpson noted no alternative cause for Petitioner's TM was found during "[a]n extensive diagnostic evaluation." Pet. Ex. 14 at 5, 9. Specifically, he noted her serum markers, including vitamin B12, were normal. Id. at 5. Therefore, he concluded that the "[flu] vaccine remains [] the only identifiable cause of [Petitioner's] TM." Id.

iv. Althen Prong Three

Dr. Simpson opined Petitioner developed "neurological symptoms [] as early as one day following [flu] vaccination," which is within the "medically acceptable time[ ]frame for the occurrence of neurological disease following vaccination." Pet. Ex. 14 at 6, 9.

Although he opined Petitioner's symptom onset was one day post-flu vaccination, Dr. Simpson questioned the accuracy of Petitioner's recall of the onset of her neurological symptoms following vaccination. Pet. Ex. 14 at 6; Pet. Ex. 28 at 3. For support, he noted Petitioner first reported her post-vaccination symptoms to a medical provider (Dr. Janeski) on October 3, 2019. Pet. Ex. 14 at 6 (citing Pet. Ex. 2 at 115). Dr. Janeski documented Petitioner's complaints "of tingling of her last [two] fingers and both feet following the flu shot." Id. (citing Pet. Ex. 2 at 115 ("[s]tat[ing] she [had] been having tingling in the last two fingers, after the flu shot last week")). Dr. Simpson noted "a specific time frame of the onset of her neurological symptoms [was] not documented" during this visit. Id.

Dr. Simpson next cited to Petitioner's visit with Dr. Whitty on October 7, 2018, where Dr. Whitty noted "onset of neurological symptoms following flu vaccination [two] weeks earlier," and Dr. Simpson again noted "a specific date of onset [was] not documented." Id. (citing Pet. Ex. 2 at 158 (noting symptoms of tingling in bilateral hands and feet was "progressively getting worse over the past [two] weeks after getting a flu shot")). Dr. Simpson next cited a record from October 11, 2019, approximately three weeks post-vaccination, when

Dr. Gilcher documented that Petitioner indicated her onset of hand paresthesias and weakness was one day after her flu vaccination. Id. (citing Pet. Ex. 8 at 18 ("The day after the flu shot [Petitioner] experienced new symptoms.")).

Dr. Simpson opined that "even if one were to assume that neurological symptoms occurred within one day of vaccination, this is a medically acceptable time frame for the occurrence of neurological disease following vaccination." Pet. Ex. 14 at 6. In his supplemental expert report, he explained he was not persuaded by Dr. Matiello's latency time frame argument. Pet. Ex. 28 at 4. He then opined Petitioner "likely [had] a recall response" given her previous flu vaccinations, explaining "[a] recall response can be swift and must be swift, otherwise immune memory would be too slow to protect us from microbial attacks." Id.

He noted the 2012 IOM report stated, "the lag phase in a memory response can begin at [one] day." Pet. Ex. 28 at 4. Specifically, he quoted the following passage from the 2012 IOM report discussing latency between antigen exposure and peak adaptive immune response:

> For both B and T cells in a typical immune response to an antigen exposure, the latency between the first (primary) exposure and development of the primary response is characterized by a lag phase, logarithmic phase, and plateau phase. The lag phase is characterized by the initial activation of B and T cells upon encounter with the antigen for which they are specific, and this triggers the cells' differentiation into effector and memory cells. The lag phase between primary exposure to an antigen and the logarithmic phase is classically thought to be [four] to [seven] days, but it varies depending on route of exposure and the antigen itself. For B cells, the logarithmic phase is characterized by an increase in serum antibody levels that classically is logarithmic. The plateau phase is characterized by the maintenance of peak antibody levels for a length of time that is followed by a decline in the serum antibody levels. For many antigens the latency (lag phase) between primary exposure and development of the primary antibody response is [seven] to 10 days. Due to the development of memory B and T cells during the primary immune response, the latency between subsequent exposure to the antigen and development of the immune response will usually be shorter. The lag phase is generally [one] to [three] days; the logarithmic phase of the secondary antibody response occurs over the next [three] to [five] days. As mentioned for the primary immune response, these time periods will vary depending on the route of exposure, the timing of the subsequent exposure, the antigen itself, and the antigen dose. While this discussion is not specific to a particular antigen, it can be used as a reference point for the latency between antigen exposure and the initiation of some of the immune-mediated mechanisms described below.

Id. (quoting Pet. Ex. 25 at 86-87).

Dr. Simpson also cited literature concerning GBS post-flu vaccination to draw inferences from TM literature "given potential similarities in pathogenetic mechanisms underlying several post-vaccination neurological disorders." Pet. Ex. 28 at 3-4; see also Pet. Ex. 14 at 6.

Schonberger et al.,[34] according to Dr. Simpson, indicated "the true range of attributable risk is both shorter than [three] days and longer than 42 days" despite the Vaccine Injury Table period of three to 42 days for GBS post-flu vaccination cases. Pet. Ex. 14 at 6 (citing Pet. Ex. 26). He cited two figures in Schonberger et al. that placed GBS cases post-flu vaccination within the first week for onset. Id. at 6-7 (citing Pet. Ex. 26 at 9 figs. 6-7). However, neither figure indicated onset by day or an onset of one day. See Pet. Ex. 26 at 9 figs. 6-7.

Schonberger et al. found "[t]he period of increased risk [for GBS] was concentrated primarily within the [five]-week period after vaccination, although it lasted for approximately [nine] or 10 weeks." Pet. Ex. 26 at 1. When the authors examined two-day intervals between vaccination and onset, from day zero to day 41, they found the largest percentage of cases occurred on day 16 and 17 day post-vaccination. Id. at 6-7, 8 fig.5. It appears eleven cases occurred between day zero (date of vaccination) to day one. See id. at 8 fig.5.

Safranek et al.[35] reassessed the findings in Schonberger et al. and excluded cases (18 vaccinated and 13 unvaccinated) of GBS that were misclassified due to onset or diagnosis. Pet. Ex. 17 at 1, 5. Upon reassessment, they found "an increased risk of developing [GBS] during the [six] weeks following vaccination in adults" and no increased risk beyond six weeks. Id. at 1. The authors noted four cases of GBS occurred within day one and day seven following vaccination. Id. at 8 tbl.3. The authors, however, did not specify whether any cases were characterized by an onset of only one day.

Dr. Simpson also cited Park et al.,[36] a study that reviewed post-vaccination GBS cases submitted to the Advisory Committee Vaccination Injury Compensation in Korea from 2002 to 2014. Pet. Ex. 27 at 1-2. During this period, 590 cases were submitted for evaluation for vaccination-related compensation. Id. at 2. Sixty-eight cases were related to GBS, and 48 of these cases were approved for compensation.[37] Id. Of these 48 cases, all had a history of flu vaccination, a previous infection could not be excluded as a causative factor in five cases, and 18 cases were classified as "possible" cases of GBS. Id. at 2, 5. The authors noted "[t]his suggest[ed] a very low incidence for vaccine-related GBS." Id. at 5. "Of the total 48 cases, 47 (97.9%) developed symptoms within [three] weeks, and in particular, more than half (54.2%) within [two] days." Id. at 2. Dr. Simpson opined "[Petitioner's] symptom onset within [one]-[three] days of flu vaccination is concordant with these findings." Pet. Ex. 14 at 7.

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[34] Lawrence B. Schonberger et al., Guillain-Barre Syndrome Following Vaccination in the National Influenza Immunization Program, United States, 1976-1977, 110 Am. J. Epidemiology 105 (1979).

[35] Thomas J. Safranek et al., Reassessment of the Association Between Guillain-Barré Syndrome and Receipt of Swine Influenza Vaccine in 1976-1977: Results of a Two-State Study, 133 Am. J. Epidemiology 940 (1991).

[36] Yong-Shik Park et al., Clinical Features of Post-Vaccination Guillain-Barré Syndrome (GBS) in Korea, 32 J. Korean Med. Sci. 1154 (2017).

[37] The authors in Park et al. included cases of "possible" GBS in their study. Pet. Ex. 27 at 5.

With regard to TM cases specifically, Agmon-Levin et al. noted 27 (73%) of the 37 reported cases of TM occurred within the first month after vaccination. Pet. Ex. 21 at 2. Two of the 37 cases occurred following flu vaccination, with onset periods of seven and nine days post-vaccination. Id. at 3 tbl.1. Fenichel mentioned two patients who developed TM seven and 29 days following flu vaccination. Pet. Ex. 20 at 4. Read et al. discussed a 50-year-old man who received a tetanus toxoid booster vaccination three weeks prior to developing TM. Pet. Ex. 22 at 1. Akkad et al. reported a patient who developed TM four days after receipt of a flu vaccine. Pet. Ex. 23 at 1. And Korn-Lubetzki et al. reported a patient who developed symptoms consistent with TM one month following flu vaccination. Pet. Ex. 24 at 1. Dr. Simpson did not provide any literature or case reports describing the onset of TM occurring one day following any vaccination.

2. Respondent's Expert, Dr. Marcelo Matiello[38]

a. Background and Qualifications

Dr. Matiello is a neuro-immunologist and board-certified neurologist who has focused his career on "clinical and biological susceptibility aspects of central nervous system (CNS) inflammatory and demyelinating disease[s], including optic neuritis, [TM], multiple sclerosis [], neuromyelitis optica spectrum disorders[,] and myelin oligodendrocyte glycoprotein antibody associated disease []." Resp. Ex. A at 1-2. After he received his M.D. in Brazil, he completed an internal medicine and neurology residency in Brazil. Resp. Ex. B at 1. Dr. Matiello then completed residencies and fellowships at the Mayo Clinic, Yale New Haven Hospital, Massachusetts General Hospital, Brigham and Woman's Hospital, and Harvard Medical School from 2006 to 2018. Id. at 1-2. He has worked as an Assistant Professor of Neurology at Harvard Medical School since 2017. Id. at 2. He has also worked as a neurologist at various hospitals since 2016 and "actively evaluate[s] and treat[s] patients with [CNS] inflammatory diseases." Resp. Ex. A at 2; see also Resp. Ex. B at 2-3. He has authored or co-authored over 50 publications during his career. Resp. Ex. A at 2; Resp. Ex. B at 28-36.

b. Opinion

Dr. Matiello opined that "based on the clinical facts and the relevant science, . . . more likely than not that [Petitioner's] vaccination is not the cause of her partial [TM] and resulting sporadic symptoms." Resp. Ex. A at 11.

i. Diagnosis

Even though Dr. Matiello found Petitioner's presentation atypical for TM due to her (1) progressive hand and feet numbness, (2) lack of sensory or muscle weakness, and (3) lack of inflammation seen with CSF, he agreed with the diagnosis of incomplete, isolated TM based on her cervical MRI. Resp. Ex. A at 6.

[38] Respondent submitted one expert report from Dr. Matiello. Resp. Ex. A.

ii. Althen Prong One

Dr. Matiello does not appear to take issue with the theory of molecular mimicry generally. See Resp. Ex. 7-11. An article Dr. Matiello cited from Walker and Abbas[39] described molecular mimicry as "the situation in which T cells that are activated by microbial peptides . . . also crossreact with self-proteins." Resp. Ex. A-5 at 6 fig.4. If "a T cell that is specific for a foreign protein is also able by chance to recognize a self-protein, . . . mounting an immune response to a pathogen might have the unfortunate side effect of triggering an autoimmune response." Id.; see also Resp. Ex. A-10 (further describing molecular mimicry and discussing vaccine-induced molecular mimicry and autoimmunity).[40]

However, Dr. Matiello takes issue with Dr. Simpson's theory because it is "not specific and does not correlate with the clinical presentation in this case." Resp. Ex. A at 7. He explained that in order for molecular mimicry to apply, "one would need to demonstrate that the inflammation in the spinal cord can be induced by exposure to a specific foreign antigen (e.g. vaccine peptide) through cross-reactive epitopes of the nervous tissue in the spinal cord." Id. at 7-8. However, "no comparison of cross-reactive epitopes (molecular structure of flu vaccine) was done for sequence or structural homology of target antigen epitopes (human spinal cord tissue)." Id. at 8.

Next, Dr. Matiello opined studies have not found a significant association between vaccines and CNS demyelinating conditions. Resp. Ex. A at 8. For support, he cited a large case control study from Langer-Gould et al.[41] examining the association of first onset CNS acute demyelinating syndromes and vaccines. Resp. Ex. A-4 at 2. Langer-Gould et al. identified 780 patients with newly diagnosed CNS acute demyelinating syndromes, with 122 patients diagnosed with TM and 33 patients diagnosed with other forms of clinically isolated syndromes.[42] Id. at 3. The authors found no association with any CNS acute demyelinating syndrome and any vaccine in the three years prior to onset. Id. "The risk of CNS [acute demyelinating syndromes] was increased 30 days after any type of vaccine in individuals younger than 50;" however, "[t]here was no association between any vaccination and CNS [acute demyelinating syndromes] in other individuals during any time interval." Id. at 3-4.

Langer-Gould et al. determined there was "no long-term association between vaccines and . . . CNS [acute demyelinating syndromes]." Resp. Ex. A-4 at 4. They further opined

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[39] Lucy S.K. Walker & Abul K. Abbas, The Enemy Within: Keeping Self-Reactive T Cells at Bay in the Periphery, 2 Nature Revs. 11 (2002).

[40] Yahel Segal & Yehuda Shoenfeld, Vaccine-Induced Autoimmunity: The Role of Molecular Mimicry and Immune Crossreaction, 15 Cellular & Molecular Immunology 586 (2018).

[41] Annette Langer-Gould et al., Vaccines and the Risk of Multiple Sclerosis and Other Central Nervous System Demyelinating Diseases, 71 JAMA Neurology 1506 (2014).

[42] The authors indicated "clinically isolated syndrome" included optic neuritis, TM, and monofocal or multifocal clinically isolated syndrome. Resp. Ex. A-4 at 3.

"[their] data do[es] not support a causal link between current vaccines and the risk of CNS [acute demyelinating syndromes]." Id. at 5. Dr. Matiello opined this finding in Langer-Gould et al. "argues against a common or uncommon molecular mimicry causal association." Resp. Ex. A at 8. The Langer-Gould et al. study did not provide data on how many of their patients with TM received the flu vaccine, or the time frame for onset of the patients.

Next, Dr. Matiello argued case reports do not establish or prove a causal relationship. Resp. Ex. A at 9. He cited Nisse and Wynn,[43] who stated, "[c]ausality cannot be inferred from an uncontrolled observation. An association does not imply a cause-effect relationship. The observation or event in question could be a mere coincidence. This is a limitation shared by all the descriptive studies." Resp. Ex. A-6 at 4. Nisse and Wynn further noted "case reports cannot be generalized" because "to generalize[,] we need both a cause-effect relationship and a representative population." Id. Based on Nisse and Wynn, Dr. Matiello opined "[t]o date, no study has shown an increased incidence of myelitis among those receiving vaccinations," and thus, any proposed association is at most "likely coincidental." Resp. Ex. A at 9 (quoting Resp. Ex. A-7 at 12-13).[44]

Dr. Matiello also cited Agmon-Levin et al. Resp. Ex. A at 9. He noted Agmon-Levin et al. "emphasized that pathogenic proof of causality was accepted only in the case of post-oral poliovirus vaccine (OPV) TM," which is a live attenuated vaccine. Resp. Ex. A at 9 (citing Pet. Ex. 21).

In conclusion, Dr. Matiello noted that well-conducted, large studies have not shown a causal association between vaccines and CNS diseases, such as TM. Resp. Ex. A at 9. Furthermore, there is a "lack of scientific proof of a true molecular mimicry between the vaccine structure and the human tissue." Id. at 10. Therefore, case reports "most likely represent coincidental temporal associations," not a causal relationship. Id.

iii. Althen Prong Two

Dr. Matiello opined that "more likely than not," Petitioner's flu vaccine did not cause her to develop TM. Resp. Ex. A at 11. He first noted, "[a]s discussed above, vaccine association is not validated by epidemiological studies, which instead substantiate the lack of association between vaccines and the development of TM." Id. at 10.

Next, with regard to Petitioner's molecular mimicry theory, Dr. Matiello took issue with the fact that testing for any specific cross-reaction was not done and therefore, the specific target for the inflammation is not known in Petitioner's case. Resp. Ex. A at 8. He noted Petitioner's diagnostic work up did not include specific testing that would determine the target for the inflammation, including testing for "antibody cross-reaction with epitopes on myelin (e.g. myelin

[43] Trygve Nissen & Rolf Wynn, The Clinical Case Report: A Review of its Merits and Limitations, 7 BMC Rsch. Notes 1 (2014).

[44] Timothy W. West et al., Acute Transverse Myelitis: Demyelinating, Inflammatory, and Infectious Myelopathies, 32 Seminars Neurology 97 (2012).

oligodendrocyte glycoprotein[] [("MOG")]) or other cells of the nervous system (e.g. water channel aquaporin-4)." Id.

Dr. Matiello added that based on "the current body of knowledge regarding the pathogenesis of immune cross-reactivity, it is reasonable to assume that the risk of autoimmunity is mainly relevant for those with previous history or family history of autoimmune diseases, subjects known to have autoantibodies, and those carrying a certain genetic profile," which he noted is not the case for Petitioner. Resp. Ex. A at 8.

Lastly, Dr. Matiello explained that while Petitioner's treating physicians may have documented a "suspected relationship" between Petitioner's flu vaccine and development of TM, "clinicians will often record their first impressions[] without the opportunity to look at the full picture in great detail, analyze it over time[,] or perform in-depth analysis of the epidemiologic and scientific literature." Resp. Ex. A at 10.

iv. Althen Prong Three

Dr. Matiello disagreed with Dr. Simpson's opinion that Petitioner's one day onset of neurological symptoms post-flu vaccination is consistent with vaccine causation. Resp. Ex. A at 10.

Specifically, Dr. Matiello disagreed with Dr. Simpson's suggestion that a one-day onset is consistent with "the most rigorously conducted epidemiological investigation of post-[flu] vaccine GBS medical literature." Resp. Ex. A at 10 (quoting Pet. Ex. 14 at 6). Dr. Matiello explained the "most common accepted timing" for onset is three to 42 days for post-flu vaccine GBS as recognized by the Vaccine Table and studies. Id. (citing 42 C.F.R. § 100.3(a); Resp. Ex. A-10 at 3).

Additionally, Dr. Matiello argued data related to timing for GBS is not specific to this case because Petitioner did not have GBS. Resp. Ex. A at 9.

Lastly, Dr. Matiello, like Dr. Simpson, discussed the latency between antigen exposure and antibody response. Resp. Ex. A at 10-11 (citing Resp. Ex. A-11);[45] see Pet. Ex. 28 at 4 (quoting Pet. Ex. 25 at 86-87). "[A]n exposure to a particular antigen[] initiates an array of reactions involving the immune system." Resp. Ex. A at 10. He explained

> [t]he lag phase between primary exposure to an antigen and the logarithmic phase is classically thought to be [four] to [seven] days, but it varies depending on route of exposure and the antigen itself. For many antigens, the latency between primary exposure and development of the primary antibody response is even higher is [seven] to 10 days. Memory B and T cells during the primary immune response—which is not proved to be the case here—the latency between subsequent exposure to the antigen and development of the immune response will

[45] Basic Concepts in Immunology, in Immunobiology: The Immune System in Health and Disease 13 (Charles A Janeway et al. eds., 5th ed. 2001).

> usually be shorter, but include a lag phase ([one] to [three] days) and the logarithmic phase of the secondary antibody response to occurs over the next [three] to [five] days.

Id. at 11.

In summary, Dr. Matiello opined that Petitioner's onset of one day "refutes the hypothesis of direct causal association of [Petitioner's] [f]lu vaccination and her TM." Resp. Ex. A at 11.

IV. DISCUSSION

A. Standards for Adjudication

The Vaccine Act was established to compensate vaccine-related injuries and deaths. § 10(a). "Congress designed the Vaccine Program to supplement the state law civil tort system as a simple, fair and expeditious means for compensating vaccine-related injured persons. The Program was established to award 'vaccine-injured persons quickly, easily, and with certainty and generosity.'" Rooks v. Sec'y of Health & Hum. Servs., 35 Fed. Cl. 1, 7 (1996) (quoting H.R. Rep. No. 908 at 3, reprinted in 1986 U.S.C.C.A.N. at 6287, 6344).

Petitioner's burden of proof is by a preponderance of the evidence. § 13(a)(1). The preponderance standard requires a petitioner to demonstrate that it is more likely than not that the vaccine at issue caused the injury. Moberly v. Sec'y of Health & Hum. Servs., 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010). Proof of medical certainty is not required. Bunting v. Sec'y of Health & Hum. Servs., 931 F.2d 867, 873 (Fed. Cir. 1991). Petitioner need not make a specific type of evidentiary showing, i.e., "epidemiologic studies, rechallenge, the presence of pathological markers or genetic predisposition, or general acceptance in the scientific or medical communities to establish a logical sequence of cause and effect." Capizzano v. Sec'y of Health & Hum. Servs., 440 F.3d 1317, 1325 (Fed. Cir. 2006). Instead, Petitioner may satisfy her burden by presenting circumstantial evidence and reliable medical opinions. Id. at 1325-26.

In particular, Petitioner must prove that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." Moberly, 592 F.3d at 1321 (quoting Shyface v. Sec'y of Health & Hum. Servs., 165 F.3d 1344, 1352-53 (Fed. Cir. 1999)); see also Pafford v. Sec'y of Health & Hum. Servs., 451 F.3d 1352, 1355 (Fed. Cir. 2006). The received vaccine, however, need not be the predominant cause of the injury. Shyface, 165 F.3d at 1351. A petitioner who satisfies this burden is entitled to compensation unless Respondent can prove, by a preponderance of the evidence, that the vaccinee's injury is "due to factors unrelated to the administration of the vaccine." § 13(a)(1)(B). However, if a petitioner fails to establish a prima facie case, the burden does not shift. Bradley v. Sec'y of Health & Hum. Servs., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

"Regardless of whether the burden ever shifts to the [R]espondent, the special master may consider the evidence presented by the [R]espondent in determining whether the [P]etitioner has established a prima facie case." Flores v. Sec'y of Health & Hum. Servs., 115 Fed. Cl. 157,

162-63 (2014); see also Stone v. Sec'y of Health & Hum. Servs., 676 F.3d 1373, 1379 (Fed. Cir. 2012) ("[E]vidence of other possible sources of injury can be relevant not only to the 'factors unrelated' defense, but also to whether a prima facie showing has been made that the vaccine was a substantial factor in causing the injury in question."); de Bazan v. Sec'y of Health & Hum. Servs., 539 F.3d 1347, 1353 (Fed. Cir. 2008) ("The government, like any defendant, is permitted to offer evidence to demonstrate the inadequacy of the [P]etitioner's evidence on a requisite element of the [P]etitioner's case-in-chief."); Pafford, 451 F.3d at 1358-59 ("[T]he presence of multiple potential causative agents makes it difficult to attribute 'but for' causation to the vaccination. . . . [T]he Special Master properly introduced the presence of the other unrelated contemporaneous events as just as likely to have been the triggering event as the vaccinations.").

B. Factual Issues

A petitioner must prove, by a preponderance of the evidence, the factual circumstances surrounding her claim. § 13(a)(1)(A). To resolve factual issues, the special master must weigh the evidence presented, which may include contemporaneous medical records and testimony. See Burns v. Sec'y of Health & Hum. Servs., 3 F.3d 415, 417 (Fed. Cir. 1993) (explaining that a special master must decide what weight to give evidence including oral testimony and contemporaneous medical records). Contemporaneous medical records, "in general, warrant consideration as trustworthy evidence." Cucuras v. Sec'y of Health & Hum. Servs., 993 F.2d 1525, 1528 (Fed. Cir. 1993). But see Kirby v. Sec'y of Health & Hum. Servs., 997 F.3d 1378, 1382 (Fed. Cir. 2021) (rejecting the presumption that "medical records are accurate and complete as to all the patient's physical conditions"); Shapiro v. Sec'y of Health & Hum. Servs., 101 Fed. Cl. 532, 538 (2011) ("[T]he absence of a reference to a condition or circumstance is much less significant than a reference which negates the existence of the condition or circumstance." (quoting Murphy v. Sec'y of Health & Hum. Servs., 23 Cl. Ct. 726, 733 (1991), aff'd per curiam, 968 F.2d 1226 (Fed. Cir. 1992))), recons. den'd after remand, 105 Fed. Cl. 353 (2012), aff'd mem., 503 F. App'x 952 (Fed. Cir. 2013).

There are situations in which compelling testimony may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. Campbell v. Sec'y of Health & Hum. Servs., 69 Fed. Cl. 775, 779 (2006) ("[L]ike any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking."); Lowrie v. Sec'y of Health & Hum. Servs., No. 03-1585V, 2005 WL 6117475, at *19 (Fed. Cl. Spec. Mstr. Dec. 12, 2005) ("[W]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent." (quoting Murphy, 23 Cl. Ct. at 733)). Ultimately, a determination regarding a witness's credibility is needed when determining the weight that such testimony should be afforded. Andreu v. Sec'y of Health & Hum. Servs., 569 F.3d 1367, 1379 (Fed. Cir. 2009); Bradley, 991 F.2d at 1575.

Despite the weight afforded to medical records, special masters are not rigidly bound by those records in determining onset of a petitioner's symptoms. Valenzuela v. Sec'y of Health & Hum. Servs., No. 90-1002V, 1991 WL 182241, at *3 (Fed. Cl. Spec. Mstr. Aug. 30, 1991); see also Eng v. Sec'y of Health & Hum. Servs., No. 90-1754V, 1994 WL 67704, at *3 (Fed. Cl. Spec. Mstr. Feb. 18, 1994) (noting Section 13(b)(2) "must be construed so as to give effect also

to § 13(b)(1) which directs the special master or court to consider the medical records (reports, diagnosis, conclusions, medical judgment, test reports, etc.), but does not require the special master or court to be bound by them").

C. Causation

To receive compensation through the Program, Petitioner must prove either (1) that she suffered a "Table Injury"—i.e., an injury listed on the Vaccine Injury Table—corresponding to a vaccine that she received, or (2) that she suffered an injury that was actually caused by a vaccination. See §§ 11(c)(1), 13(a)(1)(A); Capizzano, 440 F.3d at 1319-20. Petitioner must show that the vaccine was "not only a but-for cause of the injury but also a substantial factor in bringing about the injury." Moberly, 592 F.3d at 1321 (quoting Shyface, 165 F.3d at 1352-53).

Because Petitioner does not allege she suffered a Table Injury, she must prove a vaccine she received caused her injury. To do so, Petitioner must establish, by preponderant evidence: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." Althen, 418 F.3d at 1278.

The causation theory must relate to the injury alleged. Petitioner must provide a sound and reliable medical or scientific explanation that pertains specifically to this case, although the explanation need only be "legally probable, not medically or scientifically certain." Knudsen v. Sec'y of Health & Hum. Servs., 35 F.3d. 543, 548-49 (Fed. Cir. 1994). Petitioner cannot establish entitlement to compensation based solely on his assertions; rather, a vaccine claim must be supported either by medical records or by the opinion of a medical doctor. § 13(a)(1). In determining whether a petitioner is entitled to compensation, the special master shall consider all material in the record, including "any . . . conclusion, [or] medical judgment . . . which is contained in the record regarding . . . causation." § 13(b)(1)(A). The undersigned must weigh the submitted evidence and the testimony of the parties' proffered experts and rule in Petitioner's favor when the evidence weighs in his favor. See Moberly, 592 F.3d at 1325-26 ("Finders of fact are entitled—indeed, expected—to make determinations as to the reliability of the evidence presented to them and, if appropriate, as to the credibility of the persons presenting that evidence."); Althen, 418 F.3d at 1280 (noting that "close calls" are resolved in Petitioner's favor).

Testimony that merely expresses the possibility—not the probability—is insufficient, by itself, to substantiate a claim that such an injury occurred. See Waterman v. Sec'y of Health & Hum. Servs., 123 Fed. Cl. 564, 573-74 (2015) (denying Petitioner's motion for review and noting that a possible causal link was not sufficient to meet the preponderance standard). The Federal Circuit has made clear that the mere possibility of a link between a vaccination and a petitioner's injury is not sufficient to satisfy the preponderance standard. Moberly, 592 F.3d at 1322 (emphasizing that "proof of a 'plausible' or 'possible' causal link between the vaccine and the injury" does not equate to proof of causation by a preponderance of the evidence); Boatmon v. Sec'y of Health & Hum. Servs., 941 F.3d 1351, 1359-60 (Fed. Cir. 2019). While certainty is by no means required, a possible mechanism does not rise to the level of preponderance. Moberly, 592 F.3d at 1322; see also de Bazan, 539 F.3d at 1351.

V. CAUSATION ANALYSIS

A. Althen Prong One

Under Althen prong one, Petitioner must set forth a medical theory explaining how the received vaccine could have caused the sustained injury. Andreu, 569 F.3d at 1375; Pafford, 451 F.3d at 1355-56. Petitioner's theory of causation need not be medically or scientifically certain, but it must be informed by a "sound and reliable" medical or scientific explanation. Boatmon, 941 F.3d at 1359; see also Knudsen, 35 F.3d at 548; Veryzer v. Sec'y of Health & Hum. Servs., 98 Fed. Cl. 214, 223 (2011) (noting that special masters are bound by both § 13(b)(1) and Vaccine Rule 8(b)(1) to consider only evidence that is both "relevant" and "reliable"). If Petitioner relies upon a medical opinion to support her theory, the basis for the opinion and the reliability of that basis must be considered in the determination of how much weight to afford the offered opinion. See Broekelschen v. Sec'y of Health & Hum. Servs., 618 F.3d 1339, 1347 (Fed. Cir. 2010) ("The special master's decision often times is based on the credibility of the experts and the relative persuasiveness of their competing theories."); Perreira v. Sec'y of Health & Hum. Servs., 33 F.3d 1375, 1377 n.6 (Fed. Cir. 1994) (stating that an "expert opinion is no better than the soundness of the reasons supporting it" (citing Fehrs v. United States, 620 F.2d 255, 265 (Ct. Cl. 1980))).

The experts do not dispute the theory of molecular mimicry generally, or that it is sound and reliable. Both experts provided literature explaining the theory of molecular mimicry. See, e.g., Pet. Ex. 18 at 8; Pet. Ex. 21 at 4; Resp. Ex. A-5 at 6 fig.4; Resp. Ex. A-10. However, they dispute whether the flu vaccine specifically can cause TM via molecular mimicry.

Assuming that Petitioner has proven a sound and reliable causal mechanism under Althen prong one, the undersigned finds Petitioner did not provide preponderant evidence of a logical sequence of cause and effect or a proximate temporal relationship between the flu vaccination and Petitioner's TM. Due to the facts and circumstances of this case, specifically the fact that Petitioner developed symptoms of TM one day after receipt of a flu vaccine, the undersigned's determination as to causation turns on an analysis of Althen prongs two and three, and thus, the undersigned focuses on Althen prongs two and three. See Vaughan ex rel. A.H. v. Sec'y of Health & Hum. Servs., 107 Fed. Cl. 212, 221-22 (2012) (finding the special master's failure to rule on Althen prong one not fatal to his decision because Althen prong two was fatal to Petitioner's case); Hibbard v. Sec'y of Health & Hum. Servs., 698 F.3d 1355, 1364 (Fed. Cir. 2012) ("discern[ing] no error in the manner in which the special master chose to address the Althen [prongs]" when he focused on Althen prong two after "assuming the medical viability of [the] theory of causation").

While the undersigned is not making a finding as to whether Petitioner has provided preponderant evidence of Althen prong one, the undersigned notes that a one-day onset is not compatible with the theory of molecular mimicry. See, e.g., Forrest v. Sec'y of Health & Hum. Servs., No. 14-1046V, 2019 WL 925495, at *6, *8 (Fed. Cl. Spec. Mstr. Jan. 28, 2019) (finding "a preponderance of the evidence shows that molecular mimicry is not likely to happen within 36 hours, even for a recall response"); Martinez v. Sec'y of Health & Human Servs., No. 16-736V,

2022 WL 4884923, at *27 (Fed. Cl. Spec. Mstr. Sept. 9, 2022) (finding "a relative short onset" of one day "not medically acceptable" because "TM is reasonable understood to be mediated by an autoimmune reaction involving antibodies or other immune cells associated with the adaptive[] [] immune response in reaction to antigenic exposure" (emphasis omitted)).

B. Althen Prong Two

Under Althen prong two, Petitioner must prove by a preponderance of the evidence that there is a "logical sequence of cause and effect showing that the vaccination was the reason for the injury." Capizzano, 440 F.3d at 1324 (quoting Althen, 418 F.3d at 1278). "Petitioner must show that the vaccine was the 'but for' cause of the harm . . . or in other words, that the vaccine was the 'reason for the injury.'" Pafford, 451 F.3d at 1356 (internal citations omitted).

In evaluating whether this prong is satisfied, the opinions and views of the vaccinee's treating physicians are entitled to some weight. Andreu, 569 F.3d at 1367; Capizzano, 440 F.3d at 1326 ("[M]edical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a 'logical sequence of cause and effect show[s] that the vaccination was the reason for the injury.'" (quoting Althen, 418 F.3d at 1280)). Medical records are generally viewed as trustworthy evidence, since they are created contemporaneously with the treatment of the vaccinee. Cucuras, 993 F.2d at 1528. Petitioner need not make a specific type of evidentiary showing, i.e., "epidemiologic studies, rechallenge, the presence of pathological markers or genetic predisposition, or general acceptance in the scientific or medical communities to establish a logical sequence of cause and effect." Capizzano, 440 F.3d at 1325. Instead, Petitioner may satisfy her burden by presenting circumstantial evidence and reliable medical opinions. Id. at 1325-26.

The undersigned finds there is not preponderant evidence in the record to support a logical sequence of cause-and-effect showing the September 19, 2019 flu vaccine to be the cause of Petitioner's TM. See Althen, 418 F.3d at 1278.

First, the records show a clinical course that is not consistent with the mechanism presented due to Petitioner's onset of one day. Petitioner received a Tdap vaccine on September 19, 2019. She reported to multiple treating providers that she developed neurological symptoms one day later on September 20, 2019. See, e.g., Pet. Ex. 3 at 108 (presenting to Dr. Kasza at the Oakwood ED and stating "that the morning following . . . the vaccination, she woke with paresthesia in her [fourth] and [fifth] upper extremity digits bilaterally as well as paresthesia in her bilateral feet"); Pet. Ex. 8 at 18 (reporting to Dr. Gilcher that her symptoms "began the day following the flu shot"); Pet. Ex. 10 at 1 (reporting to Dr. Delly that on "Sept[ember] 19[] she went to go see her doctor and got the flu shot" and "[t]he next day, she started to get tingling in her fingers and toes"); Pet. Ex. 4 at 39, 41 (returning to Oakwood ED and complaining of "'nerve pain' [in] [bilateral] hands and feet since receiving the flu shot on [September 19, 2019]"); Pet. Ex. 4 at 60 (reporting to Dr. Zazaian that she developed "a pins and needles sensation in her fourth and fifth digits of bilateral hands along with her toes" on September 20, 2019); Pet. Ex. 4 at 69 (maintaining "her symptoms first developed on [September 20, 2019]" during a consultation with Dr. Kodrik). The undersigned finds an onset of one day inconsistent

with the theory of molecular mimicry for the reasons described in the Althen prong three analysis.

Second, although Petitioner's treating physicians documented an association, the undersigned does not find the notes to be persuasive evidence of causation.

On October 23, 2019, Dr. Junn found the MRI "[f]indings nonspecific[,] however suspect[ed] to be demyelinating in nature or inflammatory in nature considering presentation of symptoms following flu vaccine[,] however clinical correlation is recommended." Pet. Ex. 4 at 103. In this statement, although he notes a temporal association, Dr. Junn does not provide the reasons that he suspects the flu vaccine as a cause.

The other provider who documented an association was Dr. Kodrik. Dr. Kodrik noted Petitioner's cervical spine MRI was consistent with "[TM] from recent flu[] vaccination." Pet. Ex. 4 at 104. However, Dr. Kodrik does not explain her statement that attributes causation to the flu vaccine.

On December 19, 2019, Dr. Kodrik wrote a letter stating "[Petitioner] is under my neurologic care and is unable to receive the [flu] vaccination as she has a history of [TM] associated with the [flu] vaccination." Pet. Ex. 5 at 20. And in another letter, dated September 23, 2021, Dr. Kodrik's office wrote "[Petitioner] received the flu vaccine back in 2019 and she had a reaction in which caused the [TM]. [Petitioner] should be exempt from receiving the Covid [v]accine as this reaction does not occur again." Pet. Ex. 11 at 54. Again, in these letters, Dr. Kodrik offers no explanation for the basis of her opinions. Further, she does not explain how an immune response to the flu vaccine could result in symptoms of TM in the time frame of one day.

Generally, treating physician statements are typically "favored" as treating physicians "are likely to be in the best position to determine whether a 'logical sequence of cause and effect show[s] that the vaccination was the reason for the injury.'" Capizzano, 440 F.3d at 1326 (quoting Althen, 418 F.3d at 1280). However, no treating physician's views bind the special master, per se; rather, their views are carefully considered and evaluated. § 13(b)(1); Snyder, 88 Fed. Cl. at 746 n.67. "As with expert testimony offered to establish a theory of causation, the opinions or diagnoses of treating physicians are only as trustworthy as the reasonableness of their suppositions or bases." Welch v. Sec'y of Health & Hum. Servs., No. 18-494V, 2019 WL 3494360, at *8 (Fed. Cl. Spec. Mstr. July 2, 2019).

The balance of these statements appear to be based on the proximity and temporal association between vaccination and TM. A "treating physician's recognition of a temporal relationship does not advance the analysis of causation." Isaac v. Sec'y of Health & Hum. Servs., No. 08-601V, 2012 WL 3609993, at *26 (Fed. Cl. Spec. Mstr. July 30, 2012), aff'd, 108 Fed. Cl. 743 (2013), aff'd, 540 Fed. App'x 999 (Fed. Cir. 2013). And a temporal relationship between a vaccine and an injury, standing alone, does not constitute preponderant evidence of vaccine causation. See, e.g., Veryzer v. Sec'y of Health & Hum. Servs., 100 Fed. Cl. 344, 356 (2011) (explaining that "a temporal relationship alone will not demonstrate the requisite causal

link and that [P]etitioner must posit a medical theory causally connecting the vaccine and injury"), aff'd, 475 Fed. App'x 765 (Fed. Cir. 2012).

Lastly, although it appears the parties agree there was no identifiable alternative cause, this fact alone does not reach the level of preponderance Petitioner must meet in order to satisfy the second Althen prong. de Bazan, 539 F.3d at 1351-52.

Accordingly, the undersigned finds that Petitioner has not satisfied her burden under Althen prong two.

C. Althen Prong Three

Althen prong three requires Petitioner to establish a "proximate temporal relationship" between the vaccination and the injury alleged. Althen, 418 F.3d at 1281. That term has been defined as a "medically acceptable temporal relationship." Id. The Petitioner must offer "preponderant proof that the onset of symptoms occurred within a time frame for which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact." de Bazan, 539 F.3d at 1352. The explanation for what is a medically acceptable time frame must also be consistent with the theory of how the relevant vaccine can cause the injury alleged (under Althen Prong One). Id.; Koehn v. Sec'y of Health & Hum. Servs., 773 F.3d 1239, 1243 (Fed. Cir. 2014); Shapiro, 101 Fed. Cl. at 542; see Pafford, 451 F.3d at 1358.

Petitioner received her flu vaccination on September 19, 2019. The parties and experts generally agree that Petitioner's onset of neurological symptoms began one day later, on September 20, 2019. Although Dr. Simpson questions the accuracy of Petitioner's recall of the onset of her neurological symptoms, Petitioner's medical records consistently place Petitioner's onset the day after her flu vaccination, even if the specific calendar date is not mentioned in some records. Petitioner's declaration maintains her symptoms began on September 20, 2019, the day after vaccination. Petitioner also noted her job as a nurse and how she "[u]tiliz[ed] [her] own medical training" to ensure she was providing accurate information to providers. Pet. Ex. 35 at ¶ 9. For these reasons, the undersigned finds onset to be on September 20, 2019, one day after vaccination.

In Dr. Simpson's first expert report, he opines that a one-day onset is medically acceptable. In his second expert report, he opines that Petitioner "likely [had] a recall response" given her previous flu vaccinations. Pet. Ex. 28 at 4. However, Dr. Simpson did not explain "recall response" or how it could account for an onset of one day.

Both experts cited similar literature describing the latency period[46] between antigen exposure and peak adaptive immune response. This literature explains that with subsequent exposures—i.e., multiple flu vaccinations—the latency period is shorter, with a lag phase[47] of one to three days followed by a logarithmic phase[48] of three to five days, resulting in a latency period ranging from four to eight days.

There are several problems with Petitioner's position as to prong three. First, in order to conclude that there was a shortened latency period due to the recall response, foundational evidence is needed to establish that Petitioner received prior flu vaccinations that contained the same antigens as those she received in her 2019 flu vaccination. Although the records show that she received prior flu vaccinations, there is no evidence to show what strains of the flu were in each vaccine she received, or what antigens were in any of the prior vaccinations or the 2019 vaccination. Thus, there is no evidence that Petitioner had repeated exposures to the same antigens that were in the 2019 vaccination that she received.

Second, a latency period "is characterized by a lag phase, logarithmic phase, and plateau phase." Pet. Ex. 25 at 87. Petitioner failed to explain how this would allow for an onset of one day. Dr. Simpson only stated that the 2012 IOM report "states that the lag phase in a memory response can begin at [one] day." Pet. Ex. 28 at 4. However, Dr. Simpson did not consider both the lag phase and the logarithmic phase together. And he did not explain how a shortened lag phase, reflecting activation of B and T cells upon an encounter for the antigen for which they were specific, would translate to the initial manifestation of symptoms Petitioner experienced on September 20, 2019. In other words , Dr. Simpson failed to account for all of the phases of the latency period, that period between vaccination and manifestation of symptoms, or explain how they could occur in one day.

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[46] A latent period is "a seemingly inactive period, such as that between exposure to an infection and manifestation of symptoms (incubation p[eriod]) or between the presentation of a stimulus and the response (latency [])." Latent Period, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=97284 (last visited Mar. 1, 2024). Latency refers to "the time between the instant of stimulation and the beginning of a response." Latency, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=27698 (last visited Mar. 1, 2024). The IOM explained "the latency between the first (primary) exposure and development of the primary response is characterized by a lag phase, logarithmic phase, and plateau phase." Pet. Ex. 25 at 87. "[T]he latency between subsequent exposure to the antigen and development of the immune response will usually be shorter. The lag phase is generally [one] to [three] days; the logarithmic phase of the secondary antibody response occurs over the next [three] to [five] days." Id.

[47] A lag phase is characterized by "activation of B and T cells upon encounter with the antigen for which they are specific, and this triggers the cells' differentiation into effector and memory cells." Pet. Ex. 25 at 87.

[48] "For B cells, the logarithmic phase is characterized by an increase in serum antibody levels that classically is logarithmic." Pet. Ex. 25 at 87.

Additionally, Petitioner's one-day onset of symptoms is not consistent with the case reports cited by Dr. Simpson. In Agmon-Levin et al., the two patients who developed TM post-flu vaccination had onset periods of seven and nine days. Fenichel mentioned two patients who developed TM seven and 29 days following flu vaccination. Read et al. discussed a case of TM three weeks following a tetanus toxoid booster vaccination. Akkad et al. reported a patient who developed TM four days after receipt of a flu vaccine. And Korn-Lubetzki et al. reported a patient who developed symptoms consistent with TM one month after flu vaccination. None of the literature provided by Petitioner supports a one-day onset of TM.

Dr. Simpson attempts to rely on GBS data to support his opinion that a one-day onset is medically acceptable. He cited to Schonberger et al., who found approximately 11 cases of GBS occurred between day zero (date of vaccination) and day one. However, Schonberger et al. did not explain or discuss these cases and thus, there are foundational concerns about whether the data is reliable or applicable in the context of TM, which affects the spinal cord and is a different illness than GBS, which is a peripheral nervous system demyelinating illness.

Further, when Safranek et al. reassessed the findings in Schonberger et al., they noted four cases of GBS that occurred between day one and day seven after vaccination, and did not examine the cases in two-day intervals like Schonberger et al. Nor did they provide data on the specific onsets for those four cases. Thus, the undersigned does not find this data persuasive as she is unable to analyze or confirm the data presented.

Dr. Simpson also cited Park et al., a study from Korea that found more than half of their 48 cases developed symptoms of GBS within two days of flu vaccination. However, the authors included cases of "possible" GBS and they acknowledged they could not exclude a possible infection as a cause in some cases. Thus, it is impossible to determine whether their cases with an onset within two days had "possible" GBS or an infection. Additionally, the cases in Park et al. likely received a different flu vaccine since all of the cases occurred in Korea.

Moreover, the onset period for GBS following flu vaccination as set forth in the Vaccine Injury Table is three to 42 days. 42 C.F.R. § 100.3(a)(XIV)(D). Thus, even if the undersigned used GBS data for this TM case, the timing would be inconsistent.

Lastly, the undersigned notes decisions from other special masters where petitions alleging vaccine-induced TM in the Program have been dismissed for similar onset found too close in time to vaccination to be medically reasonable. See, e.g., Palattao v. Sec'y of Health & Hum. Servs., No. 13-591V, 2019 WL 989380, *35 (Fed. Cl. Spec. Mstr. Feb. 4, 2019) (citing dismissals of cases with 24-hour onset for vaccine-related TM and finding a 30- to 36-hour onset to not be medically acceptable); Forrest, 2019 WL 925495, at *6, *8 (finding "a preponderance of the evidence shows that molecular mimicry is not likely to happen within 36 hours, even for a recall response"); Mosley v. Sec'y of Health & Human Servs., No. 08-724V, 2015 WL 2354316, at *19 (Fed. Cl. Spec. Mstr. Apr. 27, 2015) (denying compensation where "onset of TM one day after tetanus vaccination [was] too soon to support vaccine causation"); Jagoe v. Sec'y of Health & Human Servs., No. 08-678V, 2012 WL 13036265, at *28 (Fed. Cl. Spec. Mstr. Aug. 3, 2012) (finding a 24-hour onset not medically appropriate for a vaccine-induced TM injury); Crosby v.

Sec'y of Health & Human Servs., No. 08-799V, 2012 WL 13036266, at *38-39 (Fed. Cl. Spec. Mstr. June 20, 2012) (same).

While the above cases are not binding here, the undersigned agrees with the reasoning of other special masters as it relates to onset and Althen prong three. See Boatmon, 941 F.3d at 1358; Hanlon v. Sec'y of Health & Hum. Servs., 40 Fed. Cl. 625, 630 (1998), aff'd, 191 F.3d 1344 (Fed. Cir. 1999).

In Forrest, Petitioner's expert proposed that the flu vaccine can cause TM via molecular mimicry. 2019 WL 925495, at *3. To explain the 36-hour onset, Petitioner's expert proposed the Forrest Petitioner had a recall response due to previous flu vaccinations. Id. at *4. The special master found that "[e]ven if molecular mimicry could be accepted to explain how the flu vaccine can cause [TM] abstractly, . . . a preponderance of the evidence shows that molecular mimicry is not likely to happen within 36 hours, even for a recall response." Id. at *6. The special master similarly discussed the IOM report that referenced the immune response latency period to include a lag phase and logarithmic phase. Id. Petitioner's expert in Forrest, like Dr. Simpson, "cited the IOM for the basis that the lag phase generally can be as short as one day," but failed to persuasively address the logarithmic phase and the timing and presentation of symptoms associated with the logarithmic phase.[49] Id.

Petitioner attempts to cite to "a number of additional [P]rogram cases in which Petitioners have been awarded entitlement to damages with an onset of initial symptoms between one and four days." Pet. Reply at 9-10. However, these cases either do not relate to TM or do not rely on molecular mimicry, and they are therefore not relevant to the facts and circumstances here.

In summary, the undersigned finds by preponderant evidence that the onset of Petitioner's TM was September 20, 2019, one day after her flu vaccination. Further, there is a lack of preponderant evidence to show that an onset of one day is appropriate given the proposed mechanism of molecular mimicry.

Therefore, the undersigned finds the temporal association is not appropriate given the mechanism of injury. Petitioner has failed to satisfy the third Althen prong.

VI. CONCLUSION

The undersigned extends her sympathy to Petitioner for all that she has suffered due to her TM. The undersigned's Decision, however, cannot be decided based upon sympathy, but rather on the evidence and law.

[49] Forrest also provides a more thorough explanation of the latency period of the immune response and the lag and logarithmic phases. See Forrest, 2019 WL 925495, at *6-7. In the present case, these concepts were not discussed.

For the reasons discussed above, the undersigned finds that Petitioner has failed to establish by preponderant evidence that the flu vaccination she received caused her to develop TM. Therefore, Petitioner is not entitled to compensation and the petition must be dismissed.

In the absence of a timely filed motion for review pursuant to Vaccine Rule 23, the Clerk of Court **SHALL ENTER JUDGMENT** in accordance with this Decision.

IT IS SO ORDERED.

s/Nora Beth Dorsey
Nora Beth Dorsey
Special Master